

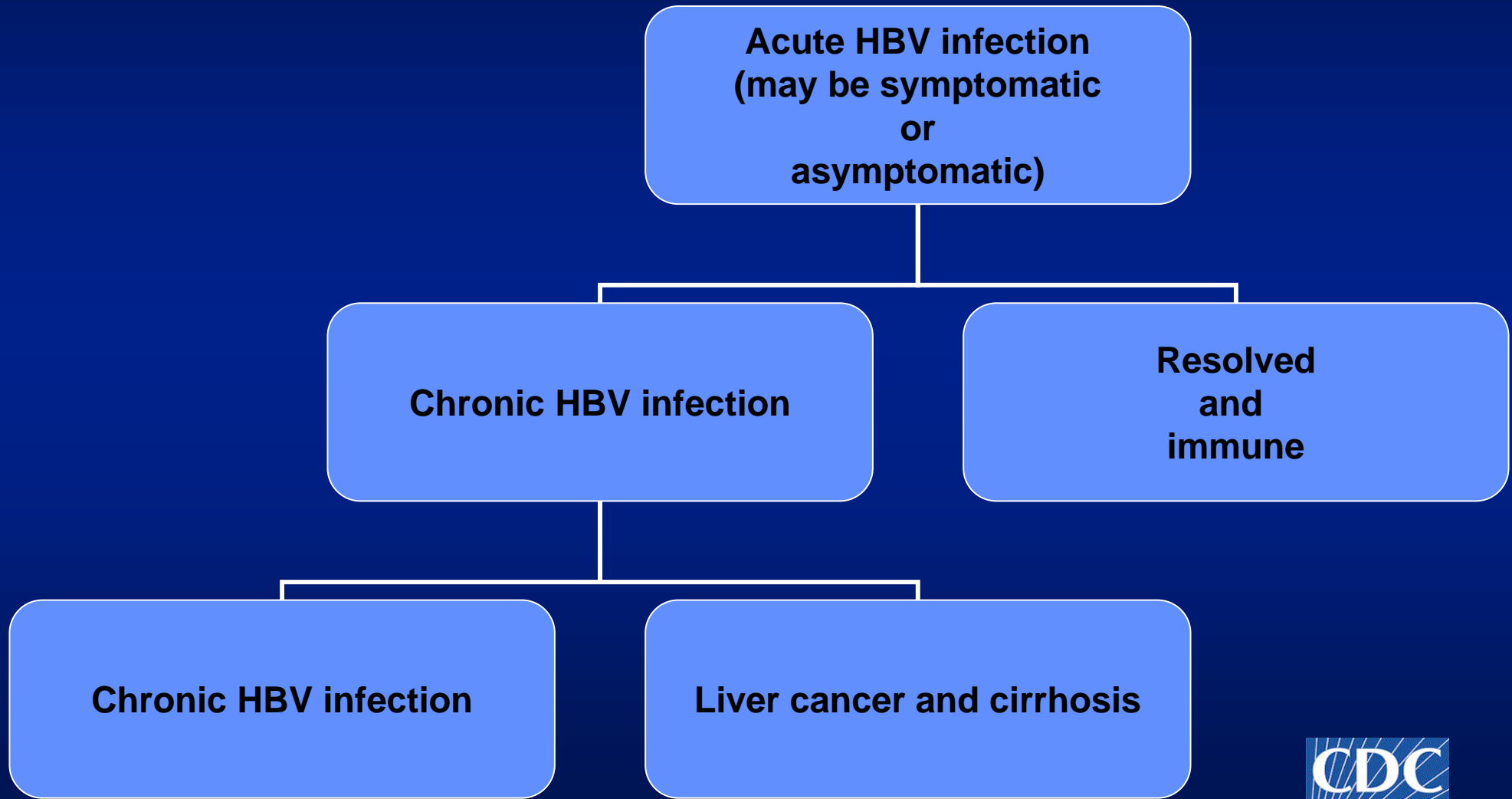
Preventing Perinatal Hepatitis B in the United States

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Natural History of Hepatitis B Virus (HBV) Infection



Burden of Disease: Hepatitis B in the U.S.

- ~60,000 new infections in 2004, down from 200,000-300,000 before hepatitis B vaccination programs
- 1 of 20 persons have been infected with HBV during their lifetime (12.5 million)
- 1 of 200 persons have chronic HBV infection (about 1.25 million)
- Annually, 4000-5000 deaths from hepatitis B-related chronic liver disease (cirrhosis, liver cancer)

Perinatal Hepatitis B in the U.S.

- ~24,000 infants were born to HBV-infected mothers in 2004
- Without immunoprophylaxis:
 - ~9100 chronically infected with HBV (most asymptomatic)
 - ~2300 expected to die of chronic liver disease
- Perinatal HepB prevention programs are very cost-effective:
 - \$3 saved (medical and work-loss costs) for every \$1 spent (program costs)
 - 1 death prevented for every 15 infants of HBV-infected mothers who are identified and given postexposure immunoprophylaxis

Natural History of HBV Infection

- Very dependent on age of infection
- Among infected children, symptomatic acute hepatitis B rare; likelihood of developing chronic infection high:

<u>Age at infection</u>	<u>Risk of acute HBV</u>	<u>Risk of chronic HBV</u>
<1 year	<1%	90%
1-5 years	5-15%	25-50%
>5 years	20-50%	6-10%

- Most morbidity and mortality associated with HBV (cirrhosis, hepatocellular carcinoma) occurs in persons with chronic infection and is usually not apparent until adulthood

Modes of HBV Transmission in Infancy and Early Childhood

- **Vertical** transmission from infected mother to infant
- **Horizontal** transmission from infected household contact to child
- *Both modes of transmission can be prevented by vaccination of newborns!*

Vertical Transmission

- Transmission from infected mother to infant
- Percutaneous and permucosal exposure to mother's blood during birth
- *In utero* transmission rare: accounts for <2% of perinatal infections
- HBV not transmitted by breastfeeding

Risk of Vertical HBV Transmission by Serologic Status of Mother

Serostatus of Mother

HBsAg

Positive

Positive

HBeAg

Positive

Negative

Infants Infected

70% - 90%

5% - 20%

Hepatitis B surface antigen or HBsAg:
marker of acute and chronic HBV infection

Hepatitis B e antigen or HBeAg:
marker of viral replication



Prevention of Vertical HBV Transmission

- Without immunoprophylaxis, approximately 40% of infants born to HBV-infected mothers in the U.S. will develop chronic HBV infection
- Postexposure prophylaxis (PEP) includes:
 - hepatitis B vaccine & hepatitis B immune globulin (HBIG) at birth
 - completion of hepatitis B vaccine series
- **PEP is highly effective in preventing vertical HBV transmission:** when given soon after birth, hepatitis B vaccine + HBIG is 85-95% effective; hepatitis B vaccine alone at birth is 70-95% effective



Horizontal Transmission

- Transmission occurring during early childhood is a result of horizontal transmission of HBV within households
 - **to** young children **from** family members: usually infected parents, older siblings, and household members
 - may be associated with breaks in skin, e.g., scabies, dermatitis
- In contrast to HIV, HBV is resistant to drying, ambient temperatures, and alcohol and can remain stable on environmental surfaces for at least 7 days

Prevention of Horizontal Transmission

- Before perinatal hepatitis B prevention programs, 61-66% of children with chronic HBV infection in the U.S. were born to uninfected mothers
- Hepatitis B vaccination at birth will **prevent horizontal transmission** in early childhood

Rationale for Hepatitis B Vaccine Birth Dose for All Infants

- Provides “**safety net**” for prevention of **vertically** transmitted HBV infections among children born to HBsAg-positive women
- Prevents early childhood HBV infections, including **horizontally** transmitted infections among children born to HBsAg-negative women
- Has been associated with higher rates of on-time completion of hepatitis B vaccine series, and in certain populations, with higher completion rates of other vaccines

Chronology of Advisory Committee on Immunization Practices (ACIP) Perinatal Hepatitis B Prevention Recommendations

- 1977 – Infants born to mothers with acute HBV infection in the third trimester of pregnancy and HBsAg seropositivity at the time of delivery may be given HBIG or IG within 7 days of birth
- 1981 – All infants born to HBsAg-positive mothers should receive HBIG within 24 hours after birth
- 1982 – Infants born to HBsAg-positive mothers should receive HBIG at birth and HepB vaccine beginning at 3 months of age
- 1985 – Mothers belonging to risk groups should be tested for HBsAg; infants born to HBsAg-positive women should receive HBIG and HepB vaccine within 12 hours of birth
- 1988 – **All** pregnant women should be screened for HBsAg
- 1991 – Routine infant hepatitis B vaccination recommended
- 2002 – Preference for birth dose stated
- 2005 – **Universal birth dose** recommended



The Perinatal Hepatitis B Prevention Program

- Funded by CDC's National Immunization Program since 1990
 - 64 project areas (50 states, 6 cities, 8 territories)
- In 1990, the objectives were to promote
 - Prenatal screening of all pregnant women for HBsAg, and
 - Case-management and tracking of infants born to HBsAg-positive mothers to assure that these infants received appropriate postexposure prophylaxis



Current Activities of the Perinatal Hepatitis B Prevention Program

- Identification of HBsAg-positive pregnant women
 - ✓ Review laboratory reporting of all positive HBsAg results for women of child-bearing age; ascertain pregnancy status of women through healthcare providers
- Case-management and tracking of infants born to HBsAg-positive mothers
 - ✓ Ensure HBIG and hepatitis B vaccine at birth, completion of vaccination series, post-vaccination serologic testing of infant
- Work with hospitals to achieve universal hepatitis B vaccine birth dose coverage
- Evaluation of hospital perinatal hepatitis B prevention practices through medical record reviews
- Identification, screening, and vaccination of susceptible household and sexual contacts

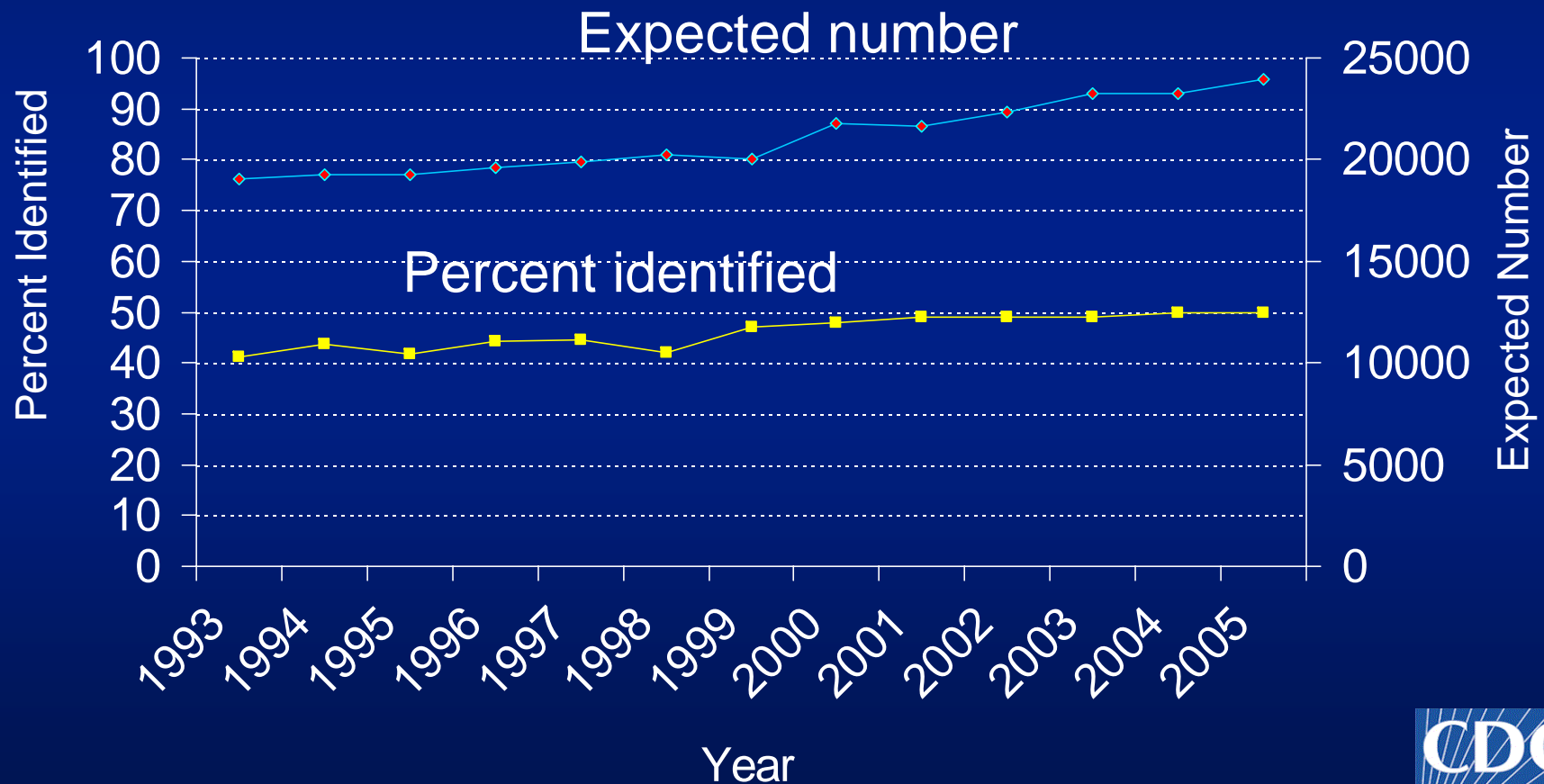
Results of Current Activities of the Perinatal Hepatitis B Prevention Program



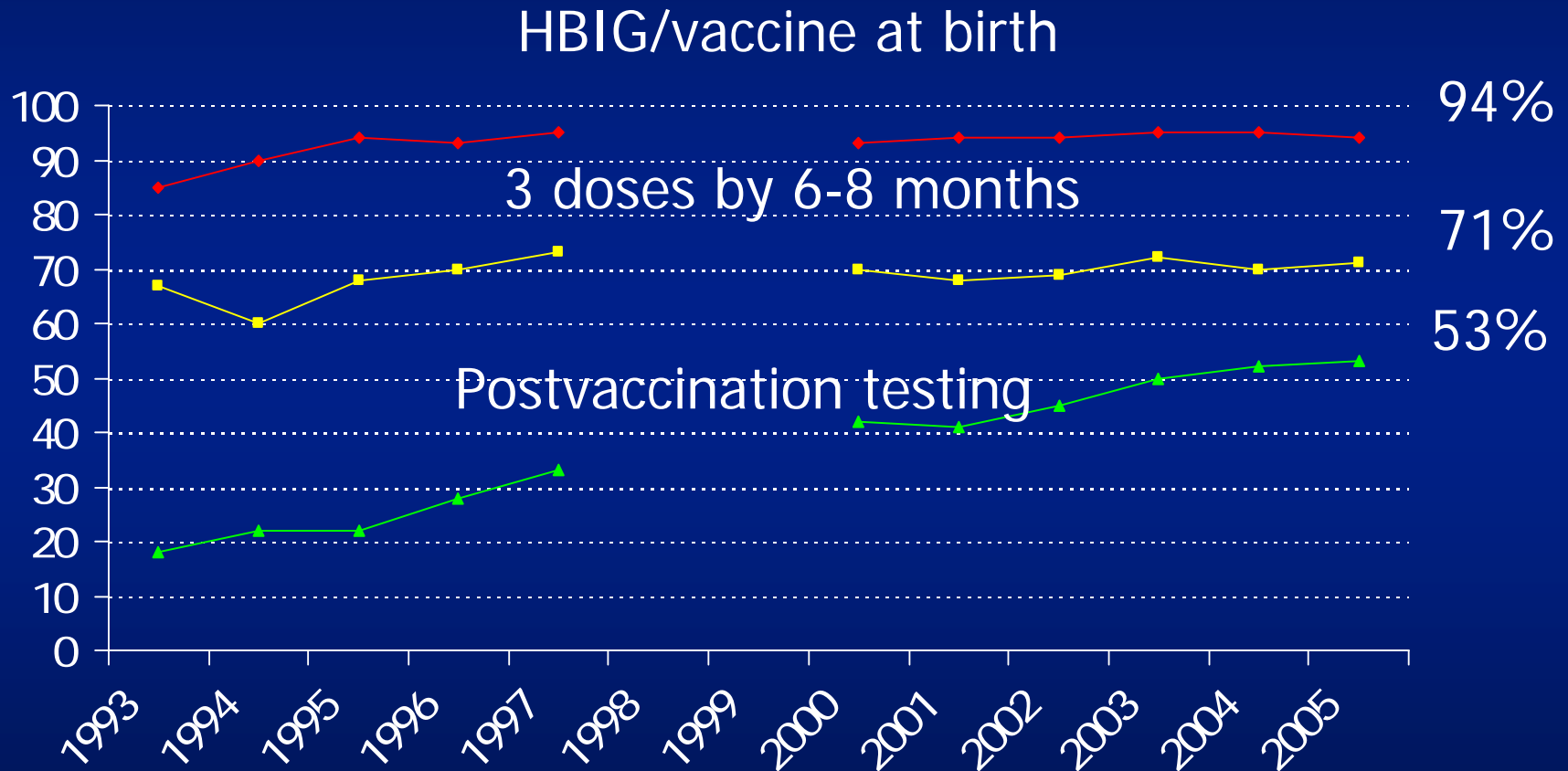
HBsAg Testing of Pregnant Women in the United States

- In 2004, immunization programs reported that 85-100% of pregnant women in their jurisdictions were screened for HBsAg
- Currently,
 - 24 states have laws requiring HBsAg screening of pregnant women
 - 24 states have laws specifically requiring the reporting of HBsAg-positive pregnant women

Identified and Expected Births to HBsAg-Positive Mothers, United States, 1993-2005



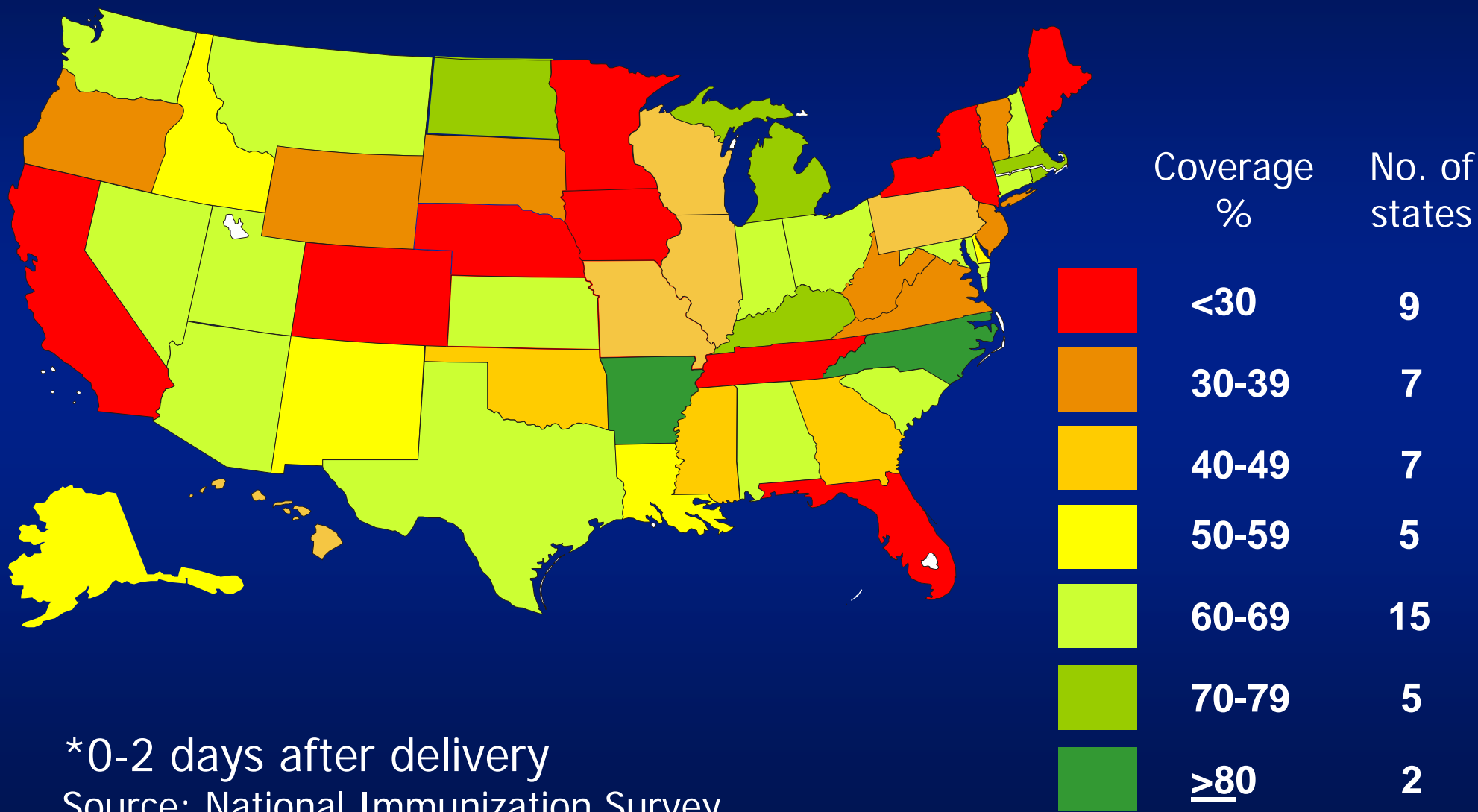
Completion of Follow-up For Infants of HBsAg-Positive Mothers, 1993-2005



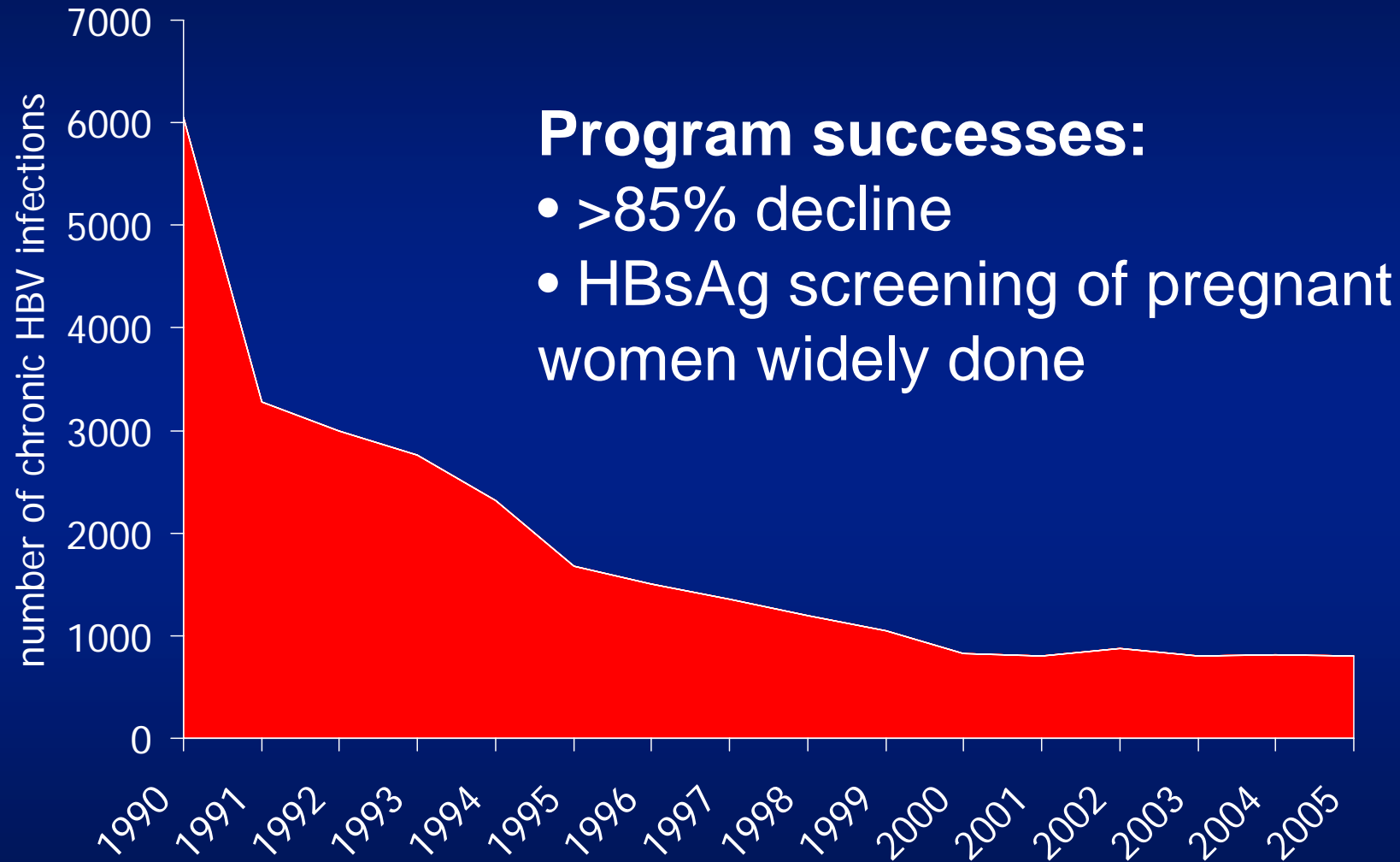
Source: National Immunization Program, CDC



Hepatitis B Vaccine Birth Dose Coverage*, 2004



Estimated New Perinatal Chronic HBV Infections United States, 1990-2005



Perinatal Hepatitis B Prevention Program Gaps, Part A

- HBsAg screening of pregnant women is not 100%
- Even with maternal screening, testing errors and lapses in transcription and reporting have resulted in cases of missed postexposure prophylaxis
- According to the National Immunization Survey, national hepatitis B vaccine birth dose rates remain <50%

2005 ACIP Hepatitis B Vaccine Recommendations for Infants, Children, and Adolescents



- Past focus on increasing maternal screening
- New **focus on hospital as safety net** to eliminate perinatal hepatitis B transmission through use of standard orders for
 - ✓ universal birth dose administration
 - ✓ universal verification of maternal HBsAg screening (requiring copy of laboratory report of test result)
- New recommendation to refer HBV-infected mother for medical care

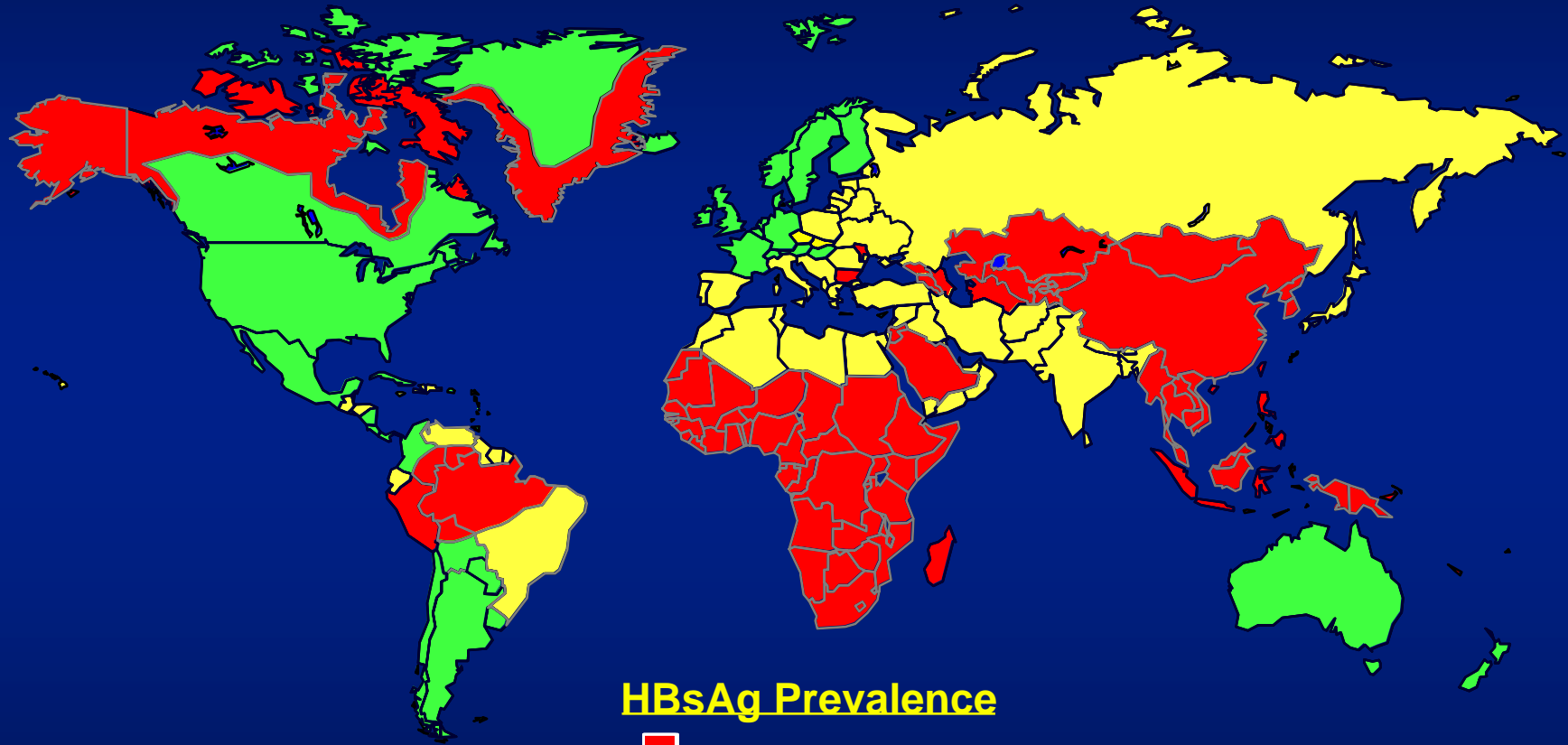
Perinatal Hepatitis B Prevention Program Gaps, Part B

- Only ~50% of expected infants born to HBsAg-positive mothers identified for case-management
- Completion rate of case management to document HBIG and 3 vaccine doses by 6-8 months is 71% and completion rate to document infant serologic test results is 53%

Challenges due to Population Trends

- Ongoing immigration from intermediate and high HBV-endemic countries
- Among the 3 project areas with the highest numbers of HBsAg-positive pregnant women, foreign-born women account for ~80% of HBsAg-positive pregnant women in CA and NYC, and 48% in TX
- Successful case management for immigrant populations requires addressing
 - Culture and customs
 - Language barriers
 - Access to health care

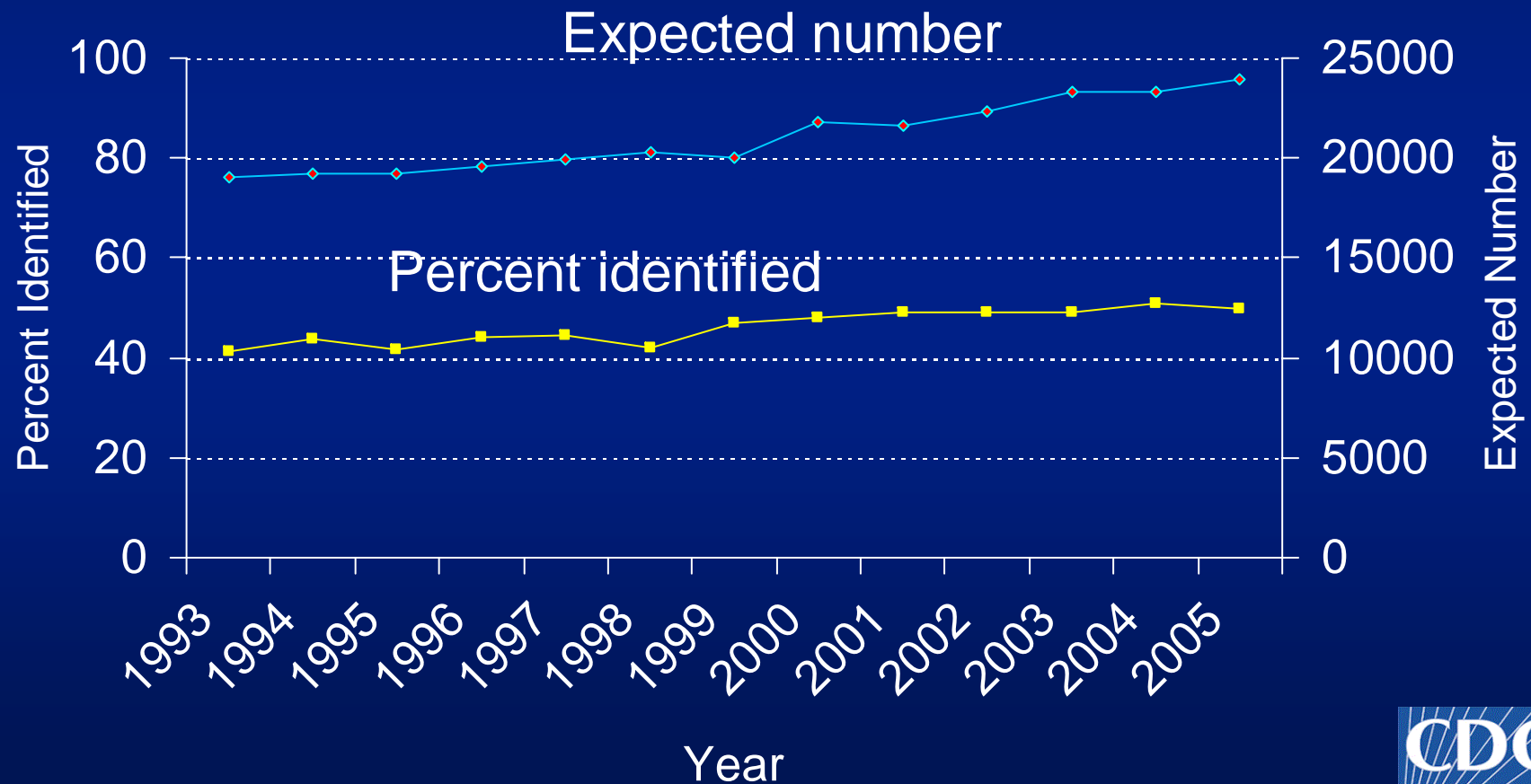
Geographic Distribution of Chronic HBV Infection



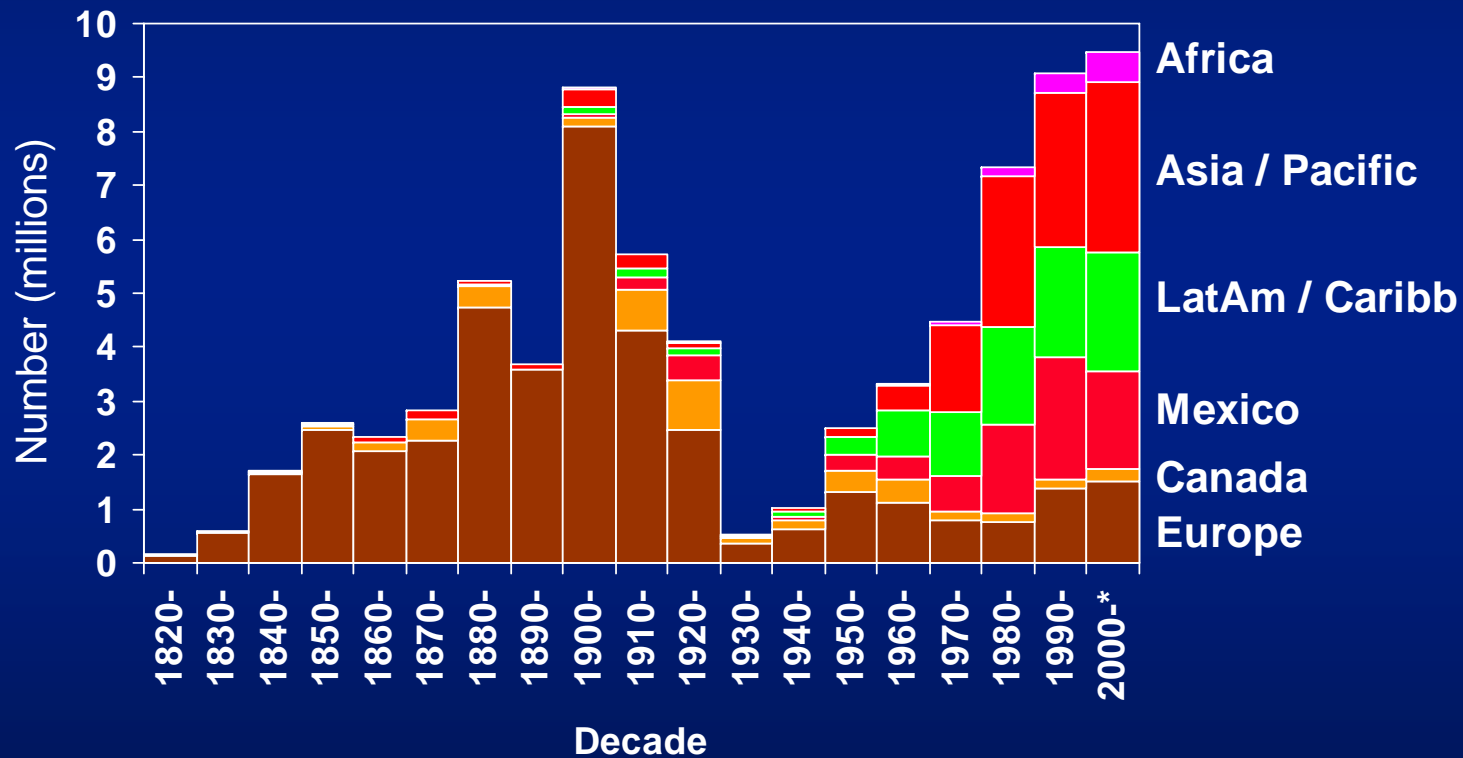
HBsAg Prevalence

- ≥8% - High
- 2-7% - Intermediate
- <2% - Low

Identified and Expected Births to HBsAg-Positive Mothers, United States, 1993-2005



U.S. Immigrants, 1820-2004



*Projected based on 2001-2004 data



Perinatal Hepatitis B Prevention Program Partners

- Asian Liver Center (ALC) at Stanford University
 - Addresses hepatitis B and liver cancer in the Asian and Pacific Islander community through: 1) outreach and education, 2) treatment, and 3) liver cancer research
 - Resource for patient education material in 6 languages
 - <http://liver.stanford.edu>
- The Immunization Action Coalition (IAC)
 - Works to increase immunization rates and prevent disease
 - Resource for educational materials for health professionals and patients, including brochures, periodicals, listservs (e.g., Hep Express)
 - The Hepatitis B Coalition, an IAC program, promotes hepatitis B vaccination, HBsAg screening of pregnant women, and education and treatment of people with chronic HBV infection
 - <http://www.immunize.org>

Summary and Conclusions

- Substantial progress has been achieved
 - >85% decline in perinatal HBV infections
- There will be ongoing need for prevention programs
 - Number of HBsAg-positive mothers increasing as a result of immigration from HBV-endemic countries
- Next steps:
 - Improve identification of HBsAg-positive mothers
 - Increase completion of case management
 - Achieve universal birth dose coverage
 - Strengthen program evaluation
 - Improve partnerships and collaboration to enhance care for mothers and children

Disclaimer: The findings and conclusions in this presentation have not been formally disseminated by CDC and should not be construed to represent any agency determination or policy.

